TRSF2

Tina-quant Transferrin ver.2

cobas®

Specific proteins

Order information

REF	CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
03015050 122	Tina-quant Transferrin ver.2 (100 tests)	System-ID 07 6567 8	COBAS INTEGRA 400 plus

Materials required (but not provided):

11355279 216	Calibrator f.a.s. Proteins (5 × 1 mL)	System-ID 07 6557 0	
11355279 160	Calibrator f.a.s. Proteins (5 × 1 mL, for USA)	System-ID 07 6557 0	
10557897 122	Precinorm Protein (3 × 1 mL)	System-ID 07 9105 9	
10557897 160	Precinorm Protein (3 × 1 mL, for USA)	System-ID 07 9105 9	
11333127 122	Precipath Protein (3 × 1 mL)	System-ID 07 9106 7	
11333127 160	Precipath Protein (3 × 1 mL, for USA)	System-ID 07 9106 7	
05117003 190	PreciControl ClinChem Multi 1 (20 × 5 mL)	System-ID 07 7469 3	
05947626 190	PreciControl ClinChem Multi 1 (4 × 5 mL)	System-ID 07 7469 3	
05947626 160	PreciControl ClinChem Multi 1 (4 × 5 mL, for USA)	System-ID 07 7469 3	
05117216 190	PreciControl ClinChem Multi 2 (20 × 5 mL)	System-ID 07 7470 7	
05947774 190	PreciControl ClinChem Multi 2 (4 × 5 mL)	System-ID 07 7470 7	
05947774 160	PreciControl ClinChem Multi 2 (4 × 5 mL, for USA)	System-ID 07 7470 7	
20756350 322	NaCl Diluent 9 % (6 × 22 mL)	System-ID 07 5635 0	

English

System information

Test TRSF2, test ID 0-567

Intended use

In vitro test for the quantitative immunological determination of human transferrin in serum and plasma on COBAS INTEGRA systems.

Summary[1,2,3,4,5]

Transferrin is a glycoprotein with a molecular weight of 79570 daltons. It consists of a polypeptide strand with two N-glycosidically linked oligosaccharide chains and exists in numerous isoforms. The rate of synthesis in the liver can be altered in accordance with the body's iron requirements and iron reserves.

Transferrin is the iron transport protein in serum. In cases of iron deficiency, the degree of transferrin saturation appears to be an extremely sensitive indicator of functional iron depletion. The ferritin levels are depressed when there is a deficiency of storage iron. In sideropenia, an iron deficiency can be excluded if the serum transferrin concentration is low, as in inflammations or - less commonly - in cases of ascorbic acid deficiency. In screening for hereditary hemochromatosis, transferrin saturation provides a better indication of the homozygous genotype than does ferritin. The treatment of anemia with erythropoietin in patients with renal failure is only effective when sufficient depot iron is present. The best monitoring procedure is to determine transferrin saturation during therapy. Transferrin saturation in conjunction with ferritin gives a conclusive prediction of the exclusion of iron overloading in patients with chronic liver disease.

A variety of methods are available for determining transferrin including radial immunodiffusion, nephelometry and turbidimetry. The Roche transferrin assay is based on the immunological agglutination principle.

Test principle

Immunoturbidimetric assay[6,7,8]

Human transferrin forms a precipitate with a specific antiserum which is determined turbidimetrically at 340 nm.

Reagents - working solutions

R1 Phosphate buffer 55 mmol/L, pH 7.2; NaCl 25 mmol/L; polyethyleneglycol (PEG) 5 %; preservative.

SR Anti-human transferrin antibodies (rabbit), dependent on titer; NaCl 100 mmol/L; preservative.

R1 is in position B and SR is in position C.

Precautions and warnings

For in vitro diagnostic use for health care professionals. Exercise the normal precautions required for handling all laboratory reagents.

Infectious or microbial waste:
Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards:
Apply all relevant local disposal regulations to determine the safe disposal.

Safety data sheet available for professional user on request.

For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

Reagent handling

Ready for use

Storage and stability

Shelf life at 2-8 °C	See expiration date on **cobas c** pack label
On-board in use at 10-15 °C	8 weeks

Specimen collection and preparation

For specimen collection and preparation only use suitable tubes or collection containers.

Only the specimens listed below were tested and found acceptable.
Serum. Collect serum using standard sampling tubes.
Plasma: Heparin (Li-, Na-, NH_4^+-) plasma.

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.

Centrifuge samples containing precipitates before performing the assay.

Samples and controls are automatically prediluted 1:21 (1 + 20) with NaCl solution by the instrument.

See the limitations and interferences section for details about possible sample interferences.

Stability:[9]	8 days at 20-25 °C
	8 days at 4-8 °C
	6 months at –20 °C

Sample stability claims were established by experimental data by the manufacturer or based on reference literature and only for the temperatures/time frames as stated in the method sheet. It is the responsibility of the individual laboratory to use all available references and/or its own studies to determine specific stability criteria for its laboratory.

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Materials provided

See “Reagents – working solutions” section for reagents.

Materials required (but not provided)

NaCl Diluent 9 %, Cat. No. 20756350322, system-ID 07 5635 0 for automatic sample and standard serial dilutions. NaCl Diluent 9 % is placed in its predefined rack position and is stable for 4 weeks on-board the COBAS INTEGRA 400 plus analyzer.

Assay

For optimum performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator’s manual for analyzer-specific assay instructions.

Application for serum and plasma

Test definition

Measuring mode	Absorbance
Abs. calculation mode	Endpoint
Reaction mode	D-R1-S-SR
Reaction direction	Increase
Wavelength A	340 nm
Calc. first/last	33/50
Typical prozone effect	> 17 g/L (> 214 µmol/L or > 1700 mg/dL)
Antigen excess check	No
Predilution factor	21
Unit	g/L

Pipetting parameters

		Diluent (H_2O)
R1	140 µL	
Sample	12.5 µL	5 µL
SR	30 µL	5 µL
Total volume	192.5 µL	

Calibration

Calibrator	Calibrator f.a.s. Proteins
Calibration dilution ratio	1:10.5, 1:21, 1:42, 1:83, 1:170, and 0 g/L performed automatically by the instrument
Calibration mode	Logit/log 5
Calibration replicate	Duplicate recommended
Calibration interval	Each lot and as required following quality control procedures.

Calibration interval may be extended based on acceptable verification of calibration by the laboratory.

Enter the assigned lot-specific transferrin value of the undiluted calibrator, indicated in the method sheet of the Calibrator f.a.s. Proteins.

Traceability: This method has been standardized with regard to the IFCC/BCR/CAP reference preparation CRM 470 (RPPHS 91/0619) for 14 serum proteins.[10]

Quality control

Reference range	Precinorm Protein or PreciControl ClinChem Multi 1
Pathological range	Precipath Protein or PreciControl ClinChem Multi 2
Control interval	24 hours recommended
Control sequence	User defined
Control after calibration	Recommended

For quality control, use control materials as listed in the “Order information” section. In addition, other suitable control material can be used.

The control intervals and limits should be adapted to each laboratory’s individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

Follow the applicable government regulations and local guidelines for quality control.

Calculation

The COBAS INTEGRA 400 plus analyzer automatically calculates the analyte concentration of each sample. For more details, please refer to Data Analysis in the Online Help.

Conversion factors:	g/L × 100 = mg/dL
	g/L × 12.6 = µmol/L

Limitations - interference

Criterion: Recovery within ± 10 % of initial value.

Icterus:[11] No significant interference up to an I index of 60 for conjugated and unconjugated bilirubin (approximate conjugated and unconjugated bilirubin concentration: 1026 µmol/L or 60 mg/dL).

Hemolysis:[11] No significant interference up to an H index of 1000 (approximate hemoglobin concentration: 621 µmol/L or 1000 mg/dL).

Lipemia (Intralipid):[11] No significant interference up to an L index of 1500. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.

Drugs: No interference was found at therapeutic concentrations using common drug panels.[12,13]

Rheumatoid factors: No significant interference from rheumatoid factors up to a concentration of 1200 IU/mL.

Other: Interference by type IgM gammopathy (Waldenström's macroglobulinemia) is recognized by the “High Activity” check. Should samples be flagged “High Act”, correct results can be obtained after postdilution.

For diagnostic purposes, the results should always be assessed in conjunction with the patient’s medical history, clinical examination and other findings.

ACTION REQUIRED

Special Wash Programming: The use of special wash steps is mandatory when certain test combinations are run together on COBAS INTEGRA analyzers. Refer to the CLEAN Method Sheet for further instructions and for the latest version of the Extra wash cycle list.

Where required, special wash/carry-over evasion programming must be implemented prior to reporting results with this test.

Measuring range

0.1-5.2 g/L (1.26-65.5 µmol/L or 10-520 mg/dL) (typical measuring range)

The upper and lower limits of the measuring range depend on the actual calibrator value.

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:2 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 2 .

Lower limits of measurement

Lower detection limit of the test:
0.1 g/L (1.26 µmol/L or 10 mg/dL)

The lower detection limit represents the lowest measurable analyte level that can be distinguished from zero. It is calculated as the value lying 3 standard deviations above that of a zero sample (zero sample + 3 SD, repeatability, n = 21).

Expected values[14]

2.0-3.6 g/L (25.2-45.4 µmol/L or 200-360 mg/dL)

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

Specific performance data

Representative performance data on the COBAS INTEGRA analyzers are given below. Results obtained in individual laboratories may differ.

Precision

Precision was determined using human samples and controls in an internal protocol with repeatability (n = 21) and intermediate precision (3 aliquots per run, 1 run per day, 10 days). The following results were obtained:

Repeatability	*Mean*	*CV*
Level 1	1.35 g/L (17.0 µmol/L or 135 mg/dL)	0.86 %
Level 2	3.36 g/L (42.3 µmol/L or 336 mg/dL)	0.77 %

Intermediate precision	*Mean*	*CV*
Level 1	1.32 g/L (16.6 µmol/L or 132 mg/dL)	1.8 %
Level 2	3.70 g/L (46.6 µmol/L or 370 mg/dL)	1.9 %

Method comparison

Transferrin values for human serum samples obtained on a COBAS INTEGRA 700 analyzer with the COBAS INTEGRA Tina-quant Transferrin ver.2 reagent (y) were compared to the same reagent on a COBAS INTEGRA 400 analyzer (x) and to those of an alternative manufacturer's automated system (nephelometric determination) (x).

		COBAS INTEGRA 400 analyzer
Sample size	(n)	74
Corr. coefficient	(r)	0.998
Lin. regression		y = 0.97x + 0.04 g/L
Passing/Bablok[15]		y = 0.97x + 0.03 g/L

The sample concentrations were between 0.35 and 4.82 g/L (4.41 and 60.7 µmol/L or 35 and 482 mg/dL).

		Alternative system
Sample size	(n)	50
Corr. coefficient	(r)	0.960
Lin. regression		y = 1.03x - 0.04 g/L
Passing/Bablok[15]		y = 1.04x - 0.08 g/L

References

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14 Dati F, Schumann G, Thomas L, et al. Consensus of a group of professional societies and diagnostic companies on guidelines for interim reference ranges for 14 proteins in serum based on the standardization against the IFCC/BCR/CAP reference material (CRM 470). Eur J Clin Chem Clin Biochem 1996;34:517-520.

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A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see dialog.roche.com for definition of symbols used):

CONTENT	Contents of kit
→	Volume after reconstitution or mixing
GTIN	Global Trade Item Number

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Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

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